

IN THE MATTER OF
US PATENT APPLICATION NO. 10/563,234
IN THE NAME OF
CHELSEA AND WESTMINSTER NHS TRUST

STATUTORY DECLARATION

I, Dr Hazem El-Refaei of 63 Waver Tree Road, London SW2 3SL, do hereby solemnly and sincerely declare as follows:-

1. I am a consultant Obstetrician and Gynaecologist at the Chelsea and Westminster Hospital and a Lead Clinician for the Hospital's Early Pregnancy Care Unit. After graduating from Cairo University, I have worked for several years as a doctor in the UK. I obtained my MD degree with merits from Aberdeen University and specialist training in Obstetrics & Gynaecology at University College of London. I am involved with the research of new treatments and the modification of established treatments in the field of Obstetrics and Gynaecology. I confirm that the information set out herein is taken from my own personal knowledge or from relevant records of documents relating thereto to which I have full access.
2. I am the inventor of US Patent Application No. 10/563,234, European patent registration number EP1641470, and PCT patent application number PCT/GB2004/002867.
3. I am also a named author on 27 research papers published in medical or scientific journals in the field of Obstetrics and Gynaecology, including studies into the use of azithromycin and misoprostol.
4. Based upon my aforementioned experience, I believe that administering vaginally a therapeutically effective amount of 250 milligrams to about 1000 milligrams of azithromycin and 50 milligrams to about 1000 milligrams of misoprostol results in a synergistic effect between these two drugs leading to the improved treatment of pelvic tissue infection and the reduction of surgical trauma resulting from a gynaecological operation.
5. Moreover, I believe that this synergistic effect is achieved throughout the aforementioned range of amounts of azithromycin and misoprostol. Namely, I believe that a synergistic effect will result from administering vaginally: 250 milligrams of azithromycin and 50 milligrams of misoprostol; 250 milligrams of azithromycin and 1000 milligrams of misoprostol; 1000 milligrams of azithromycin and 50 milligrams of misoprostol; 1000 milligrams of azithromycin and 1000 milligrams of misoprostol; and all amounts of azithromycin and misoprostol between.

6. The aforementioned synergistic effect is believed to result from the collagenolytic properties of misoprostol enhancing the delivery of azithromycin to vaginal tissue. Specifically, the collagenolytic properties of misoprostol helps to break apart collagen at the site of administration and allows for azithromycin to be more easily absorbed into the vaginal tissue. This synergistic effect between azithromycin and misoprostol thereby results in the high levels of azithromycin found in the target tissue compared to administration of azithromycin alone. Consequently, the vaginal administration of azithromycin and misoprostol provides improved treatment of pelvic tissue infection and the reduction of surgical trauma resulting from a gynaecological operation.

AND I MAKE this solemn Declaration conscientiously believing the same to be true.

Declared at..... London

this 19th day of October 2010

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